510(k) Summary

JUN 12 2009

Sponsor

Name & Address: CoAxia, Inc.
10900 73rd Avenue N. Suite 102
Maple Grove, MN 55369
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Contact: Sharon Kvistad
Vice President - Regulatory Affairs

Date Prepared: April 3, 2009

Name and Classification

Trade Name:	CoAxia FloControl™ Catheter
Common Name:	Peripheral Vascular Occlusion Balloon
Predicate Device(s):	CoAxia FloControl™ Catheter (K023914)
Classification Name:	Catheter, Intravascular Occluding, Temporary
Device Classification:	Class II
Product Code:	MJN

Intended Use:

The CoAxia FloControl Catheter is intended for use in selectively stopping or controlling blood flow in the peripheral vasculature which includes the descending aorta.

Device Description

The CoAxia FloControl™ Catheter is a 7F multi-lumen device with two balloons mounted near the distal tip. The catheter is inserted over a .035" guide wire through a 7F vascular introducer sheath. The device has a working length of 62 cm and is coated with a hydrophilic coating. A multi-port manifold at the proximal end of the device allows balloon inflation, guide wire insertion and attachment of a pressure monitoring line. Each balloon is 2 cm (20 mm) in length, separated by a distance of 8 cm. Each balloon can be inflated independently to a variable diameter to control blood flow in the selected vessel. When used in the descending aorta, balloon inflation results in diversion of cardiac output to the upper torso and core organs, e.g., cardiac, spinal and cerebral vasculature. The device has 3 marker bands to aid in balloon placement. The catheter is EtO sterilized and is intended for single use only.

Summary of Studies

The CoAxia FloControl™ Catheter was tested in accordance with relevant ISO and EN standards and FDA's Guidance for Use of Short-term and Long-term Use Intravascular Catheters. Testing included tensile strength, balloon characterization, dimensional verification, accessory compatibility, trackability, coating integrity, pressure monitoring capability, shelf life and biocompatibility. All testing demonstrated acceptable performance in accordance with the device specifications. Clinical testing of the FloControl catheter was not performed.

Equivalence Statement:

The testing performed demonstrates the CoAxia FloControl Catheter is substantially equivalent to the predicate device in terms of the intended use, design, materials, and performance attributes, and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2009

CoAxia, Inc.
c/o Ms. Sharon D. Kvistad
VP Regulatory Affairs
10900 73rd Avenue North, Suite 102
Maple Grove, MN 55369

Re: K090970
Trade/Device Name: FloControl Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: MJN
Dated: April 3, 2009
Received: April 6, 2009

Dear Ms. Kvistad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090970

Device Name: CoAxia FloControl™ Catheter

Indications For Use: The CoAxia FloControl™ Catheter is intended for use in selectively stopping or controlling flow in the peripheral vasculature, which includes the descending aorta.

Prescription Use __x__ (Part 21 CFR 801 Subpa) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vuhmes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090970